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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,063	02/28/2002	Rocco Casagrande	11641/39	7445

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WASHINGTON, DC 20005

EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 02/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/084,063

Applicant(s)

CASAGRANDE ET AL.

Examiner

David M. Naff

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-214 is/are pending in the application.
- 4a) Of the above claim(s) 1-196 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 197-214 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/20/02, 1/28 & 8/5/03</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

In a response of 12/17/04 to a restriction requirement of 9/17/04, applicants elected Group V claims 197-214 without traverse.

Claims 1-196 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/17/04.

Claims examined on the merits are 197-214.

The other documents listed on PTO-1449 of 1/28/03 have been lined through and not considered since copies of the documents did not reach the application file.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 197-214 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In line 1 of claim 197, reciting "arraying about one to about five cells into a discrete location" is confusing since it is uncertain how one cell can form an array. Additionally, if the five cells are in a discrete location, this would not be an array. Furthermore, in the last two lines of the claim, the one to five cells

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are in each of magnetic receptacles. It is uncertain how the cells being in each of the receptacles can form an array of the cells as required in line 1.

Claim 197 is unclear as to whether the one to five cells are
5 contained by magnetic receptacles of the device and are part of the device, or the cells are recited to indicate material the receptacles are capable of containing.

Claim 198 is unclear how the further experimentation defined further limits the device of claim 197. The device of claim 198 is
10 the same as that of claim 197.

Claim 201 is unclear by not having antecedent basis for "said bioaffinity ligand".

Claim 203 is unclear as to the relationship of the cell isolation device to the device of claim 197, and how these two devices function
15 together. Furthermore, the claim is unclear how the isolation device functions to isolate cells in relation to the receptacles of claim 197.

In line 1 of claim 204, there is not clear antecedent basis for "the walls", and it is unclear as to the difference in the "micro
20 through-holes" and the "micro-through-hole walls".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

25 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the

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subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 179-214 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ekenberg et al (5,567,326) in view of Dolan et al (6,136,182) and Liberti et al (6,013,532), and if necessary in further view of Zborowski et al (5,968,820) (all recited on a form PTO-1449).

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The claims are drawn to a device for arraying cells comprising a substrate having magnetic receptacles and a localized magnetic field gradient such that cells associated with magnetic beads are immobilized in each of the magnetic receptacles.

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Ekenberg et al disclose an apparatus for separating magnetically responsive particles. The apparatus contains an array of containers such as a multi well plate, a plurality of magnetically responsive pins in a pin plate that form a pin array, and a planar magnet pack

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above the pin plate. The pins are inserted in the wells, and are caused by the magnet pack to create a magnetic field that separates cells in a medium in the wells due to magnetically responsive particles attached to the cells (col 7, lines 8-27 and col 8, lines 1-40).

Dolan et al disclose a magnetic device for examination and manipulation of cells having magnets configured to provide a vertically-directed gradient so that magnetically-labeled cells are collected on an interior surface of a vessel in an ordered array. For example, see col 6, line 30 to col 7, line 40.

Liberti et al disclose magnetic immobilization and manipulation of cells. A fluid medium is placed in a vessel having a ferromagnetic capture structure including an elongated linear collection surface. The vessel is placed into a magnetic field for inducing a magnetic gradient in a region along the collection surface. Magnetically-labeled cells are attracted toward the collection surface and immobilized thereon in a linear array. For example, see the abstract and cols 5, 6 and 7.

It would have been an obvious to modify the apparatus of Ekenberg et al by replacing the pins with magnets below each well of the multi well plate so that cells labeled with magnetically responsive particles are drawn to and immobilized on the bottom surface of each well as suggested by Dolan et al using magnets configured to provide a vertically-directed gradient so that magnetically-labeled cells are collected on an interior surface of a vessel in an ordered array, and

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Liberti et al placing a vessel into a magnetic field for inducing a magnetic gradient in a region along a collection surface where magnetically-labeled cells are attracted toward the collection surface and immobilized thereon in a linear array. One would have been motivated to make this modification to provide immobilized cells in a condition to be observed and further analyzed as in Dolan et al and Liberti et al. The conditions of dependent claims would have been matters of obvious choice depending merely on individual preference in view of the disclosures of the references. Zborowski et al further disclose magnetic separation of cells, and if needed, would have further suggested conditions that can be used.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair->

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direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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David M. Naff
Primary Examiner
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DMN
2/18/05